Health Status Benefits of Transcatheter vs. Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk

Results From The PARTNER 2 Trial

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Disclosure

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Background

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- Improved quality of life (QOL) is a key goal of treatment for patients with severe AS and may be even more important than improved survival for many elderly patients
- Prior studies have shown that transcatheter aortic valve replacement (TAVR) results in substantial and durable QOL benefits in extreme risk/inoperable patients and an early QOL benefit compared with surgical aortic valve replacement (SAVR) in patients at high surgical risk
- However, the early QOL benefit of TAVR was confined to patients who were suitable for transfemoral access and was not seen in patients treated via the transapical approach

Background- 2

- In the PARTNER 2A trial, TAVR was found to be non-inferior to SAVR for the primary endpoint of 2-year death or disabling stroke among patients at intermediate surgical risk
- There were differences in procedure-related complications and valve performance at 1 year, however, with some endpoints favoring TAVR and others favoring surgical AVR
- The overall impact of these alternative treatments on health-related QOL from the patient's perspective has not yet been reported

PARTNER 2A: Patient Population

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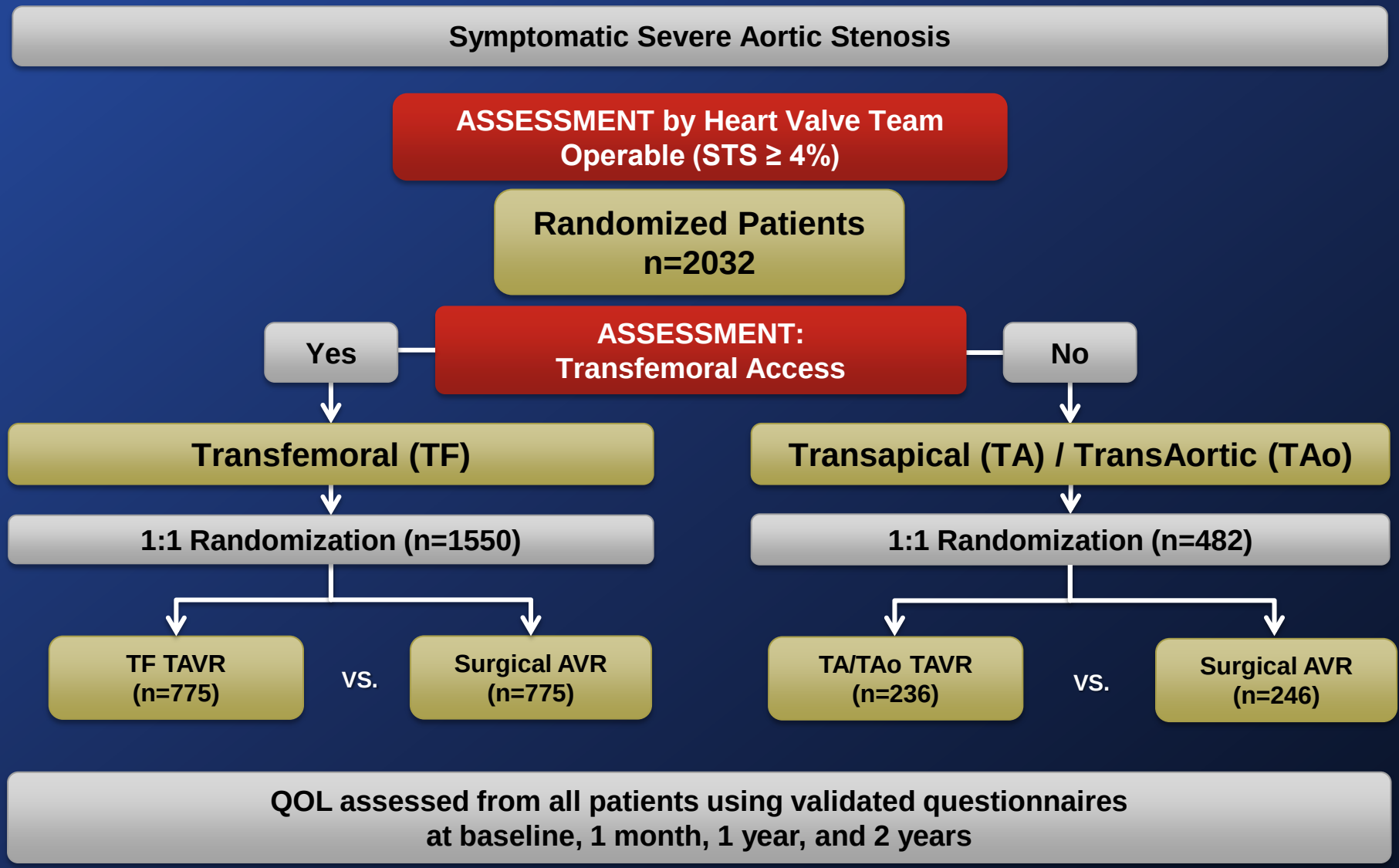
Key Inclusion Criteria

- Severe, symptomatic AS (AVA <0.8 cm2 [or AVA-I ≤0.5cm^2/m^2] and mean gradient > 40 mmHg or peak aortic jet velocity >4.0 m/sec)
- "Intermediate Risk" → Predicted risk of operative mortality ≥ 4% based on heart team assessment

Key Exclusion Criteria

- LVEF < 20%
- CAD requiring revascularization with either unprotected left main dz or SYNTAX score >32
- Serum creatinine > 3.0 mg/dl or hemodialysis
- Recent MI (1 month), stroke or TIA (6 months)

The PARTNER 2A Trial
Study Design



Statistical Methods

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- Study Population: All patients with baseline QOL data (n=1833, 90.2%)– analyzed by ITT
- Primary QOL Endpoint = KCCQ Overall Summary Score
- All other QOL scales considered secondary endpoints
- Scores between groups at each timepoint compared using analysis of covariance (ANCOVA), adjusting for baseline health status and access site
- Analytic plan specified that separate analyses would be performed for the transfemoral (TF) and transthoracic (TT) groups in case of a significant interaction between treatment effect and access site

Baseline Characteristics

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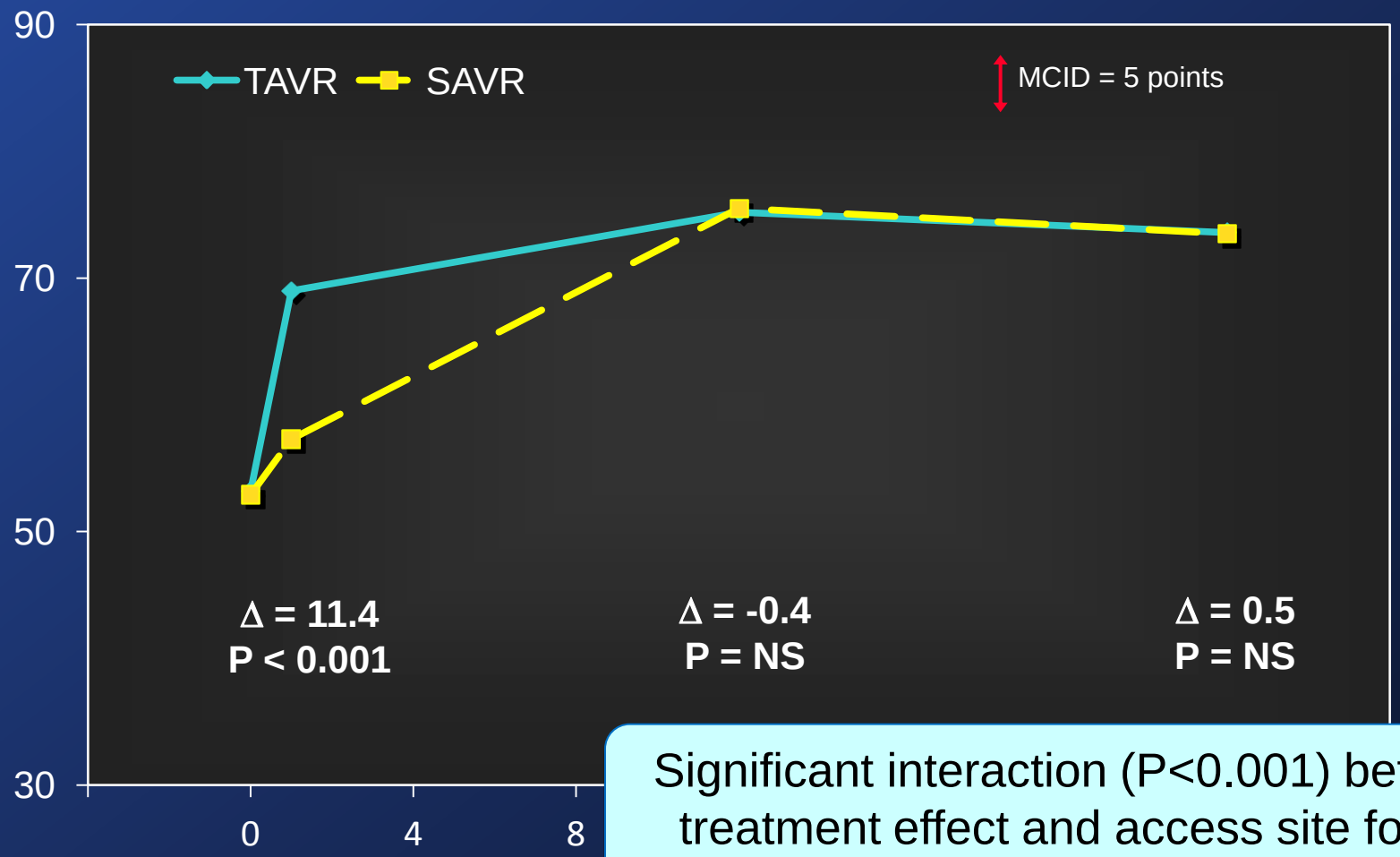
	TAVR (n = 950)	*AVR (n = 883)*
Age (yrs)	81 ± 7	81 ± 7
Male gender	54.4%	55.4%
STS risk score	5.8 ± 2.1	5.8 ± 1.8
Prior MI	18.1%	17.9%
Prior CABG	23.7%	25.6%
Prior Stroke	10.2%	10.2%
COPD (O_2 dependent)	11.2%	9.7%
Mean AVG (mmHg)	45 ± 13	45 ± 12

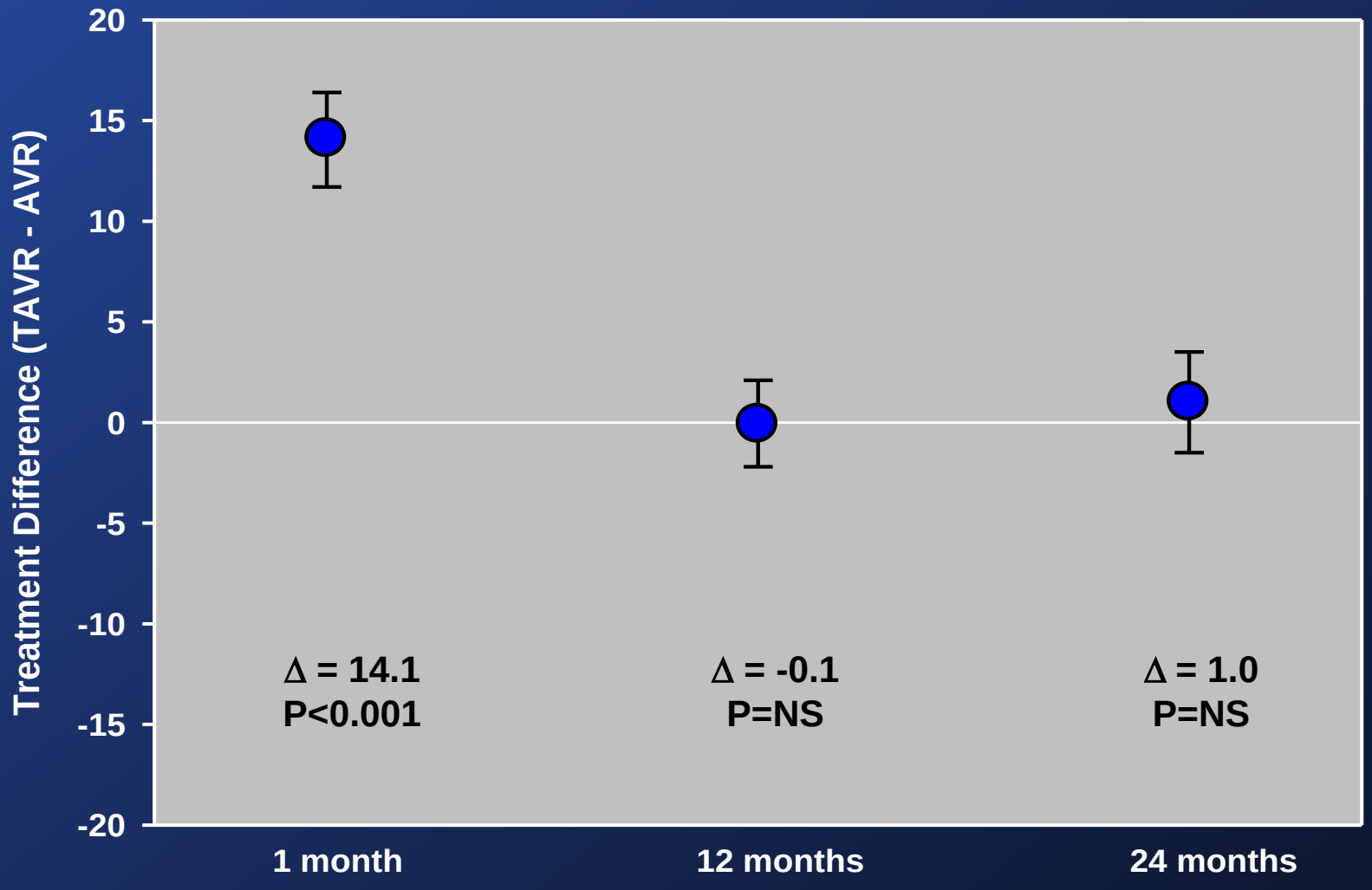
P = NS for all comparisons

Primary Endpoint
KCCQ Overall Summary



Significant interaction (P<0.001) between treatment effect and access site for the primary endpoint and multiple secondary endpoints

KCCQ Overall Summary (Primary Endpoint)
TF Subgroup



P-values are for mean treatment effect of TAVR vs. SAVR

KCCQ Overall Summary (Primary Endpoint)
TT Subgroup

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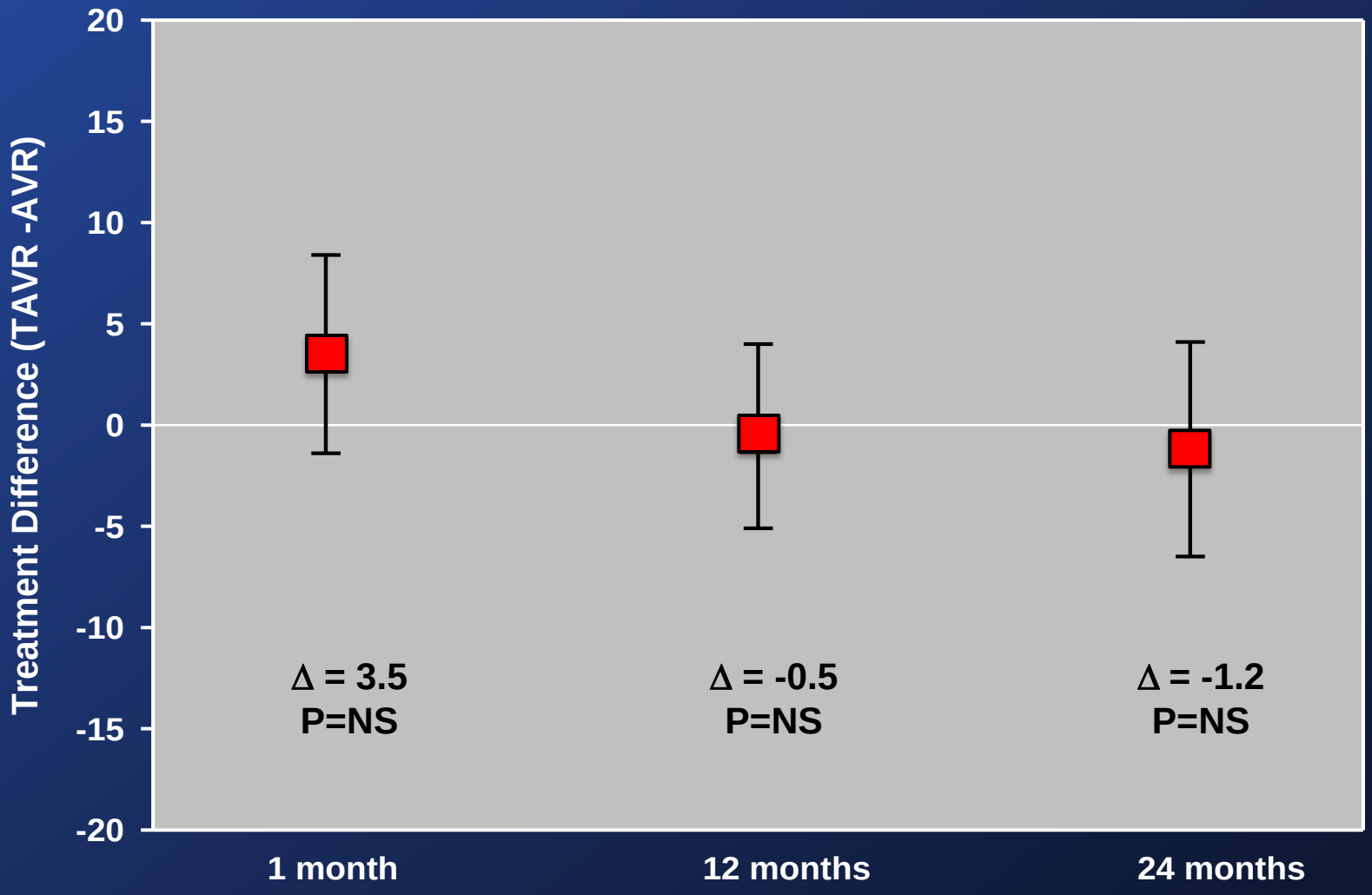

P-values are for mean treatment effect of TAVR vs. SAVR

KCCQ-Summary: Moderate or Substantial Improvement*: TF Subgroup

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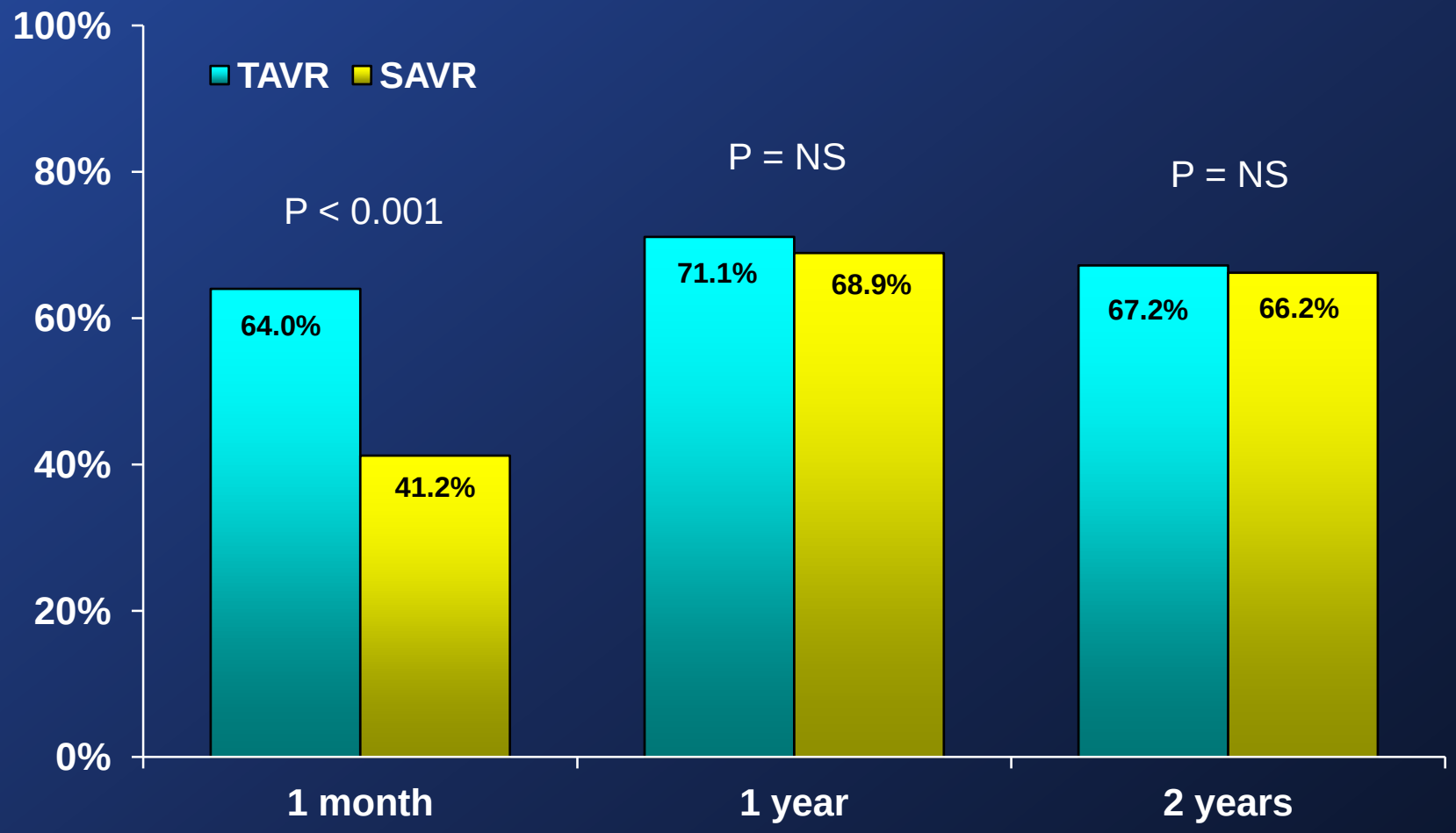
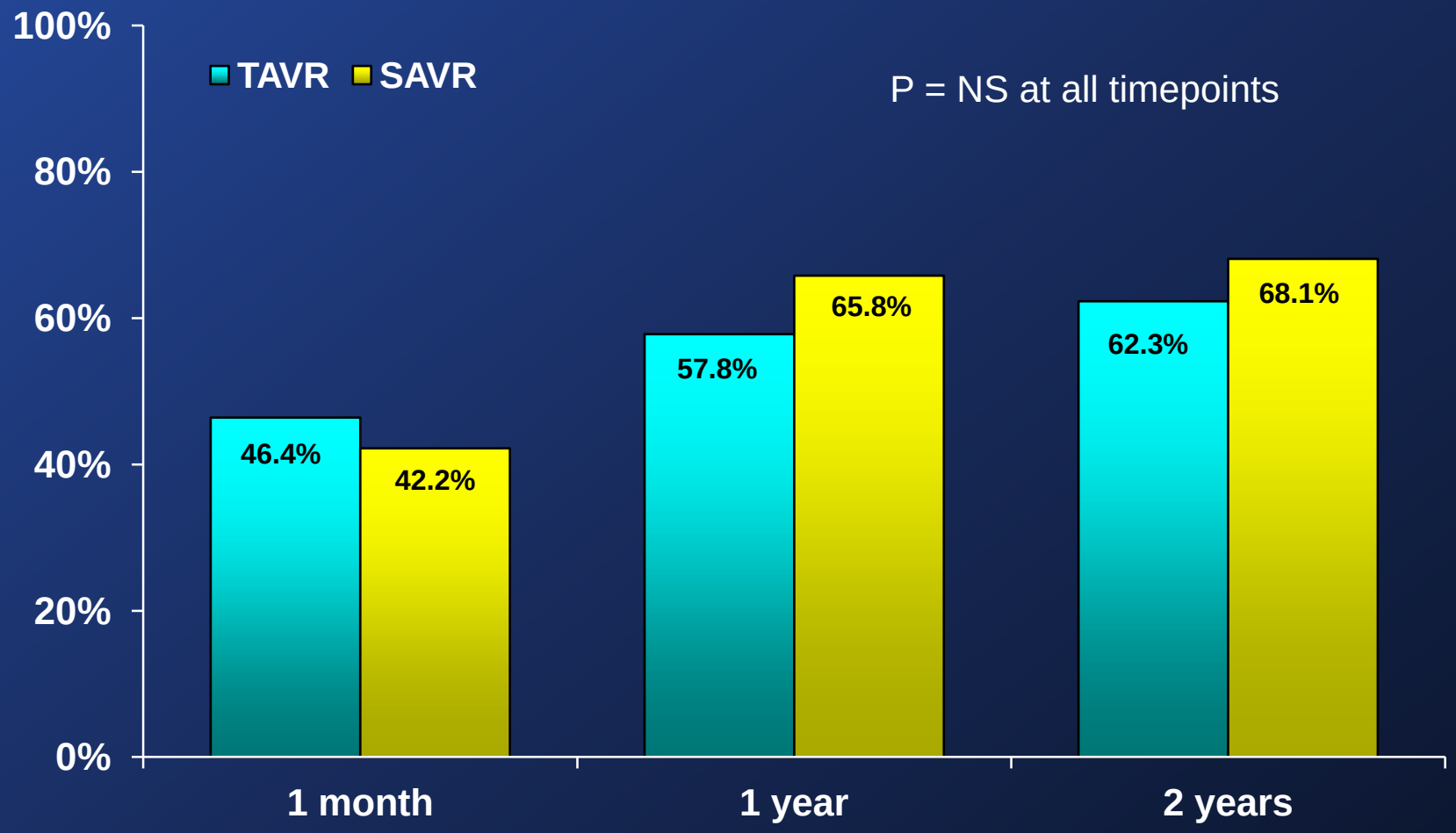


* Improvement ≥ 10 points vs. baseline among patients with available QOL data

KCCQ-Summary: Moderate or Substantial Improvement*: TT Subgroup



* Improvement ≥ 10 points vs. baseline among patients with available QOL data

Conclusions

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- Taken together with previous data, these findings demonstrate that for intermediate risk patients suitable for a TF approach, TAVR provides both early and late benefits compared with surgical AVR from the patient's perspective
- The lack of benefit among patients ineligible for the TF approach suggests that a TT approach may not be preferable to SAVR in such patients– at least in the short to intermediate term
- Further studies will be necessary to determine whether use of other alternative access sites (e.g., subclavian, carotid, transcaval) can overcome these limitations of the TT approach